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Attorney Docket No. PX3904USW

### REMARKS/ ARGUMENTS

This Amendment is submitted in response to the Office Action mailed March 14, 2003 (the Action). Currently Claims 1 and 10-15 are pending. Claims 10 and 14 have been amended to depend from Claim 1 and Claim 15 has been amended to depend from Claim 14. Applicants have added new Claims 16-27, which are fully supported by the specification at pages 2-6 and Figures 1 and 2, for example.

#### **I. Clarification of the Record**

In Applicant's response filed on March 13, 2003, Applicant's attorney set forth the argument that one of the many reasons that the present invention is not obvious over the cited references is that Applicant discovered the problem of drug deposition inside the metering valves of metered dose inhalers. Upon further reflection and review of the art of record, it is unclear as to whether Applicant discovered the problem of drug deposition inside the metering valves of metered dose inhalers. Accordingly, Applicant wants to make it clear to the Examiner that Applicant is not relying on this argument for patentability of the present invention. Applicant reserves the right to explore fully whether Applicant did, in fact, discover the problem of drug deposition inside the metering valves of metered dose inhalers and, if appropriate, renew these arguments at a later time in prosecution.

#### **II. Claims 1 and 10-15 Are Patentable Over DiGiovanni in view of Cunningham**

Claims 1 and 10-15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over WO97/16360<sup>1</sup> (DiGiovanni) in view of US Patent No. 3,709,410 to Cunningham (Cunningham). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness by combining references, the Patent Office must show (1) that one skilled in the art would be motivated to combine the references to provide the claimed invention; (2) that, when combined, there would be a reasonable expectation of success; and (3) that the prior art references, when combined, teach or suggest all of the claim limitations. Applicant submits that the Patent Office has not established a *prima facie* case of obviousness.

<sup>1</sup> See US Patent No. 6,112,950 which is an English language equivalent document filed under 35 U.S.C. 371 of the WO97/16360 document.

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**A. There is No Motivation to Combine DiGiovanni with Cunningham**

The Patent Office is required to provide clear and particular evidence showing that one skilled in the art would be motivated to combine references to arrive at the claimed invention. *See In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Patent Office has failed to establish by clear and particular evidence that one skilled in the art would be motivated to combine DiGiovanni with Cunningham to arrive at the claimed invention for at least the following reasons.

**1. There is No Motivation to Look to Cunningham for Guidance**

The Patent Office has not established by clear and particular evidence that one skilled in the art desiring to improve a metering valve for dispensing a pharmaceutical product would look to the non-metering valves of Cunningham for guidance or inspiration. Cunningham is not directed to metering valves, which typically dispense a specific amount of product for each actuation of the valve stem. Instead, Cunningham is directed to non-metering valves, which continuously dispense a product as long as the valve stem is depressed. As stated by Cunningham, such non-metering valves are typically used "for dispensing liquid substances such as hair spray, cleaners, waxes and disinfectants." (Col. 1, lines 6-7). These non-metering valves would not be used to dispense a pharmaceutical product, as recited in the present claims, because the administered dose could not be adequately controlled. Thus, one skilled in the art would not look to Cunningham for guidance or inspiration in improving a metering valve for dispensing a pharmaceutical product because Cunningham is directed to non-metering valves, which would not be useful and/or effective in dispensing pharmaceutical products.

Additionally, product deposition does not typically occur in a non-metering valve because the product does not reside in the non-metering valve for any appreciable period of time. Instead, the product passes through the valve during valve actuation and drains back down into the container when the valve is at rest. Even if product deposition were to occur in such non-metering valves, this deposition would typically not be a concern to a consumer. The consumer can simply hold the valve stem down for a longer period of time until the desired amount of product, such as hair spray, cleaners, waxes, and disinfectants, is dispensed. Thus, one skilled in the

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art would not look to Cunningham for guidance or inspiration in reducing the deposition of a pharmaceutical product on the surfaces of a metering valve because Cunningham is directed to non-metering valves, for which product deposition either does not occur or is not typically a concern. For at least the foregoing reasons, the Patent Office has not established why one seeking to reduce the deposition of a pharmaceutical product on a metering valve would look to Cunningham for guidance or inspiration.

**2. Even if One Skilled in the Art Were Motivated to Look to Cunningham for Guidance, There is Still No Motivation to Combine DiGiovanni and Cunningham**

Even if one of skill in the art were motivated to look to Cunningham for guidance, Applicant respectfully submits that the Action does not present clear and particular evidence of why one skilled in the art would be motivated to combine the DiGiovanni and Cunningham references to arrive at the claimed invention. Instead, the Action has merely made broad, conclusory statements regarding the teachings of DiGiovanni and Cunningham. "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence'." *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

The Action argues that "[i]t would have been obvious to one having ordinary skill in the art at the time of the invention to have made any of the valve structure parts, including the valve body and metering chamber of DiGiovanni et al. out of PTFE as both DiGiovanni et al. Cunningham teaches that it is well known in the dispensing valve art to make various parts (e.g. valve body and valve stem) out of Teflon™ (PTFE) in order to take advantage of Teflon's well known properties such as enhanced chemical non-reactiveness and non-stick characteristics." Such broad and conclusory statements are not evidence that would support a motivation to combine the references to arrive at the claimed invention.

Moreover, these broad and conclusory statements overstate the teachings of the references. Contrary to the assertions of the Action, both DiGiovanni and Cunningham do not teach that it is well known in the dispensing valve art to make various parts (for example, valve body and valve stem) out of Teflon™ (PTFE). Instead, DiGiovanni only proposes making a valve stem for a metering valve out of a

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mixture of acetal resin, PTFE, and silicone and Cunningham only proposes making a valve body for a non-metering valve out of a plastic, such as nylon, teflon, polystyrene, ABS, acrylic, phenolic or vinyl resin. DiGiovanni and Cunningham do not propose making any other valve parts out of PTFE. The broad and conclusory statements of the Action overstate the teachings of the references and do not provide clear and particular evidence as to why one skilled in the art would be motivated to combine the DiGiovanni and Cunningham references to arrive at the claimed invention.

The broad and conclusory statements of the Action further overstate the teachings of the references because neither DiGiovanni nor Cunningham teach making a valve part out of Teflon™ (PTFE) "in order to take advantage of Teflon's well known properties such as enhanced chemical non-reactiveness and non-stick characteristics" as asserted by the Action. Instead, these references propose the use of PTFE materials for completely different reasons.

DiGiovanni teaches that it is known in the art of metering valves to make a valve stem out of an acetal/PTFE/silicon mixture in order to reduce the amount of friction between the valve stem and the chamber seal. DiGiovanni does not describe or suggest making the valve stem out of the acetal/PTFE/silicon mixture in order to take advantage of the non-reactive or non-stick properties of the PTFE, thereby reducing or eliminating deposition of the drug product on the valve stem. In fact, DiGiovanni does not even recognize that drug deposition can occur in a metered dose valve.

As for Cunningham, the reference states, at column 3, lines 50-52, that "[v]alve body 20 may be made of a plastic material such as nylon, teflon, polystyrene, ABS, acrylic, phenolic or vinyl resin." Contrary to the assertions of the Action, Cunningham does not teach that it is well known in the dispensing valve arts to make the valve body out of Teflon™ (PTFE) "in order to take advantage of Teflon's well known properties such as enhanced chemical non-reactiveness and non-stick characteristics." Instead, Cunningham merely lists Teflon as one of many various plastics that can be used for the valve body.

In fact, Cunningham is not at all concerned with the non-reactiveness and non-stick characteristics of Teflon or any of the other plastics listed. Cunningham is instead concerned with making the valve body "of a material having sufficient

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resiliency to return the slit portions of the body to their normal position following a filling operation." (Col. 2, lines 55-58). While the resiliency of the plastic material can be critical to the operation of Cunningham's invention, (see, e.g., col. 2, lines 22-58), Cunningham does not express any desire to make a non-metering valve body out of Teflon™ (PTFE) "in order to take advantage of Teflon's well known properties such as enhanced chemical non-reactiveness and non-stick characteristics" as asserted by the Action. The Action's broad and conclusory statements overstate the teachings of the DiGiovanni and Cunningham references and do not provide clear and particular evidence as to why one skilled in the art would be motivated to combine the DiGiovanni and Cunningham references to arrive at the claimed invention.

For at least the foregoing reasons, Applicant respectfully submits that the Patent Office has not established that one skilled in the art would be motivated to combine the teachings of the DiGiovanni and Cunningham references to arrive at the claimed invention.

**B. Even if Combined, DiGiovanni and Cunningham Do Not Teach or Suggest All of the Claim Recitations**

In order to establish a *prima facie* case of obviousness, the cited references, when combined, must teach or suggest all of the claim recitations. Applicant submits that DiGiovanni and Cunningham, when combined, do not teach or suggest all of the claim recitations.

For example, while DiGiovanni proposes a metering valve assembly comprising a valve body having a metering chamber, said metering chamber including at least one metering chamber wall, said metering chamber being in communication with said dispensing channel during said actuation of the valve stem, neither DiGiovanni nor Cunningham teaches or suggests the recitations of "said metering chamber wall comprising a material selected from the group consisting of a fluorinated ethylene propylene, polytetrafluoroethylene, a copolymer of a polytetrafluoroethylene and combinations thereof" as recited in Claim 1. As described above, at most DiGiovanni proposes a valve stem comprised of a mixture of acetal resin, PTFE, and silicone and Cunningham proposes a non-metering valve body made from a plastic, such as PTFE. When combined, DiGiovanni and Cunningham do not disclose or suggest the metering chamber wall recited in Claim 1.

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Moreover, neither DiGiovanni nor Cunningham teaches or suggests a metering valve assembly "whereby substantially all of said first and second volumes of said pharmaceutical product are dispensed during said first and second actuations of said valve stem" as recited in Claim 1.

Furthermore, neither DiGiovanni nor Cunningham teaches or suggests a metering valve assembly "whereby said first and second volumes of said pharmaceutical product dispensed during said first and second actuations of said valve stem are substantially equal" as recited in Claim 1.

For at least the foregoing reasons, Applicant respectfully submits that the Patent Office has not established that DiGiovanni and Cunningham, when combined, teach or suggest all of the limitations of the claims.

**C. Conclusion**

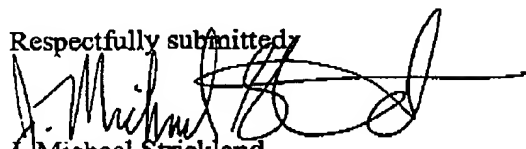
The Patent Office has not established by clear and particular evidence that one skilled in the art would be motivated to combine the DiGiovanni reference with the Cunningham reference to arrive at the claimed invention. Even if there were such a motivation to combine, the Patent Office has not established that the combination would teach or suggest all of the claim recitations. For at least the foregoing reasons, Applicant respectfully submits that the Patent Office has not established a *prima facie* case of obviousness.

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### **III. Conclusion**

For at least the foregoing reasons, Applicant respectfully submits that the claims of the present application are patentable over the cited references and respectfully requests the issuance of a Notice of Allowance forthwith. Applicant encourages the Examiner to direct any questions to the undersigned, who may be contacted at (919) 483-9024.

Respectfully submitted,

  
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Date: June 16, 2003  
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